REMARKS

Claims 1-2 and 5-13 are pending. Claims 3 and 4 were previously withdrawn. No new matter is added.

Rejection of Claims 1-11 and 13 under 35 U.S.C. § 102(b)

The Office Action rejects claims 1-11 and 13 under 35 U.S.C. §102(b) for alleged lack of novelty over Hoo *et al.*, U.S. Patent No. 5,891,432. Specifically, the Office Action alleges that Hoo *et al.* anticipates the instant invention by disclosing a composition comprising "an antigen and a fusion polypeptide [where] the antigen and the fusion polypeptide are bounded and unbounded together." Applicants respectfully traverse this rejection.

For a prior art reference to anticipate a claimed invention, the prior art must teach ***each and every element*** of the claimed invention. *Lewmar Marine v. Barient*, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987).

Hoo *et al.* fails to describe a "composition comprising an antigen bearing target and a fusion polypeptide, said fusion polypeptide comprising a first amino acid sequence which can bind to a carbohydrate and a second amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte, wherein said composition includes said fusion polypeptide bound to a carbohydrate on said antigen bearing target and includes said polypeptide ***which is not bound to said antigen bearing target***," as the instant claims require. Indeed, Applicants respectfully submit that Hoo *et al.* in no way teaches or suggests, a composition which comprises fusion polypeptide "***which is not bound to [an] antigen bearing target***," as the instant claims require.

Throughout U.S. 5,891,432 Hoo *et al.* discloses a vaccine comprising **membrane bound** immunomodulatory molecules (see abstract, column 2, line 29-30, column 9, lines 12-16, example 2 and claims 1-12). Hoo et al. defines "membrane bound" at page 9, lines 12-16 as "**stably** attached to a cellular membrane…a membrane-bound fusion protein is expressed on the surface of the cell." Clearly, a molecule that is **stably** bound to a cellular membrane is **not subject to release from the cell membrane**" and is always bound to the surface of a cell. That is, the Hoo *et al.*

reference, by requiring that a membrane bound fusion protein be "stably attached to a cellular membrane" clearly does not teach a fusion polypeptide "**which is not bound to [an] antigen bearing target**", as required by the instant claims.

Claim 1 of Hoo *et al*, which is specifically alleged in the Office Action to support the requirement of the instant claims wherein "fusion polypeptide are bounded and unbounded together" explicitly requires that the fusion polypeptide be "membrane bound", that is, stably attached to a cellular membrane. That is, claim 1 of Hoo et al. discloses a **membrane bound** fusion protein comprising GM-CSF and a membrane attachment domain. Applicants assert that claim 1 of Hoo et al. does not disclose a fusion polypeptide which is "***not bound to an antigen bearing target"*** (*e.g.*, the cell).

The Office Action also states that "[i]n the composition of Hoo, the antigen and the fusion polypeptide are bounded and unbounded together. [claim 1 and claim 12, particular.] Applicants assert that claim 12 refers to a composition comprising **membrane bound** fusion protein comprising GM-CSF fused to a heterologous membrane attachment domain, and a disease-associated antigen or immunogenic epitope fused to the membrane bound fusion protein. That is, neither of claims 1 and 12 of the Hoo *et al*. reference teaches, a composition which comprises fusion polypeptide "***which is not bound to [an] antigen bearing target***," as the instant claims require.

In contrast, the presence of fusion polypeptide which is ***not bound to an antigen bearing target*** (*e.g.*, a cell) is an indispensable element of the instant claims. At least in view of the presence of this element, the instant claims are conclusively distinguished over the Hoo *et al*. reference. Thus, Hoo *et al*. fails to anticipate the claimed invention, as it fails to disclose or suggest each and every element of the instant claims.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-11 and 13 under 35 U.S.C. § 102(b).

Rejection of Claims 1 and 12 under 35 U.S.C. § 103(a)

The Office Action rejects claims 1 and 12 under U.S.C. § 103(a) over Hoo *et al*. in view of Stray *et al*. (*Glycobiology*, 2000 Vol. 10 No. 7: 649-65) as evidenced by Rott

et al. Med. Microbiol. Immunol. 1996 184-193). Specifically, the Office Action alleges that Stray et al. teaches a cell surface receptor that is hemagglutin and hemagglutinin has a membrane attachment domain that binds to sialic acid. The Office Action also alleges that Rott *et al.* teaches that influenza hemagglutinin is a naturally occurring lectin. The Office Action further alleges that it would have been obvious to use the membrane attachment domain of hemagglutinin as a suitable alternative to the membrane attachment domain taught by Hoo.

Applicants traverse this rejection.

The Office Action has failed to establish a *prima facie* case of obviousness under the requirements of 35 U.S.C. § 103(a). To establish a *prima facie* case of obviousness, the Examiner must establish that the prior art included each element claimed (M.P.E.P. 2143). In addition, "[a] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art." *KSR International Co. v. Teleflex Inc.* 167 L. Ed. 2d 705, 712. Under section 103, "[b]oth the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure" (*Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.* 927 F.2d 1200, 1207, 18 USPQ2d 1016 (Fed. Cir. 1991), quoting *In re Dow Chemical Co.,* 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed Cir. 1988)).

The combination of Hoo *et al.* Stray *et al.* and Rott *et al.* fails to support the rejection of the claims as obvious. As set forth above, Hoo *et al.* fails to disclose or suggest a "composition comprising an antigen bearing target and a fusion polypeptide, said fusion polypeptide comprising a first amino acid sequence which can bind to a carbohydrate and a second amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte, wherein said composition includes said fusion polypeptide bound to a carbohydrate on said antigen bearing target and includes said polypeptide ***which is not bound to said antigen bearing target***," as the instant claims require. Neither of Stray *et al.* or Rott *et al.* cure this defect.

In view of all of the above, Applicants assert that the combination of the Hoo *et al.* Stray *et al.* and Rott *et al.* references fails to obviate the rejection of the instant claims. Specifically, the combination of Hoo *et al.*, Stray et al. and Rott et al. references fails to disclose or suggest a "composition comprising an antigen bearing target and a

fusion polypeptide, said fusion polypeptide comprising a first amino acid sequence which can bind to a carbohydrate and a second amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte, wherein said composition includes said fusion polypeptide bound to a carbohydrate on said antigen bearing target and includes said polypeptide ***which is not bound to said antigen bearing target***," as the instant claims require.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1 and 12 under U.S.C. § 103(a).

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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